



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1825]

Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a final guidance for industry entitled “Investigational COVID-19 Convalescent Plasma,” which was issued in April 2020 and updated in May 2020. FDA is withdrawing the guidance because the Agency is issuing a new guidance for industry of the same title.

DATES: The withdrawal is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled “Investigational COVID-19 Convalescent Plasma” (May 2020 guidance) dated April 2020 and updated May 2020. The availability of this guidance was announced in the *Federal Register* of May 26, 2020, (85 FR 31513) and was posted on FDA’s website on May 1, 2020.

On August 23, 2020, the Agency issued an emergency use authorization (EUA) (available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal->

regulatory-and-policy-framework/emergency-use-authorization#coviddrugs) for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. Given the issuance of this EUA, FDA is issuing a new guidance of the same title that provides recommendations and additional information related to the EUA for the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19. The new guidance supersedes the May 2020 guidance. Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of the new guidance.

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-20801 Filed: 9/18/2020 8:45 am; Publication Date: 9/21/2020]